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February 3, 2004

BY FEDERAL EXPRESS

ORIGINAL

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, Maryland 20852

CITIZEN PETITION

Dear Madam/Sir:

In accordance with 21 C.F.R. § 314.161, and pursuant to 21 C.F.R. §§ 10.25(a) and 10.30, I am submitting this Petition (original and three (3) copies) to request that the Commissioner of the Food and Drug Administration ("FDA" or the "Agency") determine that a drug listed in the Discontinued Drug Products section of the Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book") was voluntarily withdrawn from marketing for reasons other than safety or efficacy.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine that AstraZeneca LP's Dyclone® (dyclonine hydrochloride) Topical Solution 0.5% and 1.0% (NDA 9-925) was voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy and that, therefore, an Abbreviated New Drug Application may be submitted and approved pursuant to 21 C.F.R. §§ 314.122 and 314.161 using Dyclone® as the reference listed drug.

B. Statement of Grounds

The Orange Book identifies drug products approved by the FDA on the basis of safety and effectiveness. The current version of The Orange Book includes Dyclone® in the Discontinued Drug Product List, thus indicating that neither of the two approved formulations currently is approved for marketing. Indeed, the FDA announced in the Federal Register that the NDA holder, AstraZeneca LP, had informed the Agency that it no longer marketed the two formulations and had requested that the approval of the NDA (9-925) be withdrawn. See 67 Fed. Red. 6264 (Feb. 11, 2002).

2004P-0051

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As of the date of this submission, Dyclone® is not available in the marketplace. The petitioner is not aware of any information or other evidence that would suggest the Dyclone® was withdrawn from the market because of concerns about the products' safety or effectiveness. Further, the petitioner understands that there remains a significant demand for the products at least two years after the products' withdrawal from the market. The petitioner believes that AstraZeneca's decision to withdraw the product from the market was based on economic and/or strategic planning concerns, and not based on the safety or efficacy of the product.

C. Environmental Impact

This Petition is entitled to a categorical exclusion under 21 C.F.R. § 25.31. Therefore an environmental assessment is not required for this requested action.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only if requested by the Commissioner. The petitioner will provide such information promptly if so requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

If you have any questions concerning this Petition, please contact me.

Sincerely,

Wayne H. Matelski

Wayne H. Matelski
Arent Fox, PLLC